

**REMARKS**

Applicant thanks Examiner Finn for her time and consideration of the present application during the telephonic interview of November 21, 2011 with the undersigned.

During the interview, the enablement issues concerning the compound and compositions were discussed, as well as the rejection based on CAI.

This application is amended in manner to address the issues discussed during the interview and place the application in condition for allowance.

**Status of the Claims**

Claim 1 has been amended formally and no longer includes fluoroalkyl radical for R1 and R2 of formula I.

Claims 16-18 have been amended to remove "prevention", and claim 18 has been amended to be consistent with the lipid metabolism disorders described in the Figures of the specification.

Claims 1, 6, 7 and 14-18 remain in this application.

**Claim Rejections-35 USC §112**

Claims 1, 3-4, 6 and 13-18 stand rejected under 35 U.S.C. §112, first paragraph, for not complying with the

enablement requirement. This rejection is respectfully traversed for the reasons below.

The compounds claims 1, 6, 7 and 14 meet the enablement requirement, as the specification describes how to make such compounds, for example, by the reaction described in the paragraph bridging pages 20 and 21. The specification also describes how to use these compounds, for example, for the inhibition of intracellular lipid vesicles on page 17, lines 3-17 and Table 1. Thus, the compounds described by claims 1, 6, 7 and 14 meet the enablement requirement.

The composition claims 15-18, which include compounds according to claim 1, also comply with the enablement requirement, as the specification describes how to make the pharmaceutical compositions of claim 15, for example, with pharmaceutically acceptable excipients, solvents, etc. on pages 18-19. The specification further explains how to use such composition, e.g., for the treatments of lipid metabolism disorders outlined in claim 18 according to pages 18 and 19 and further the following figures as outlined in the table below:

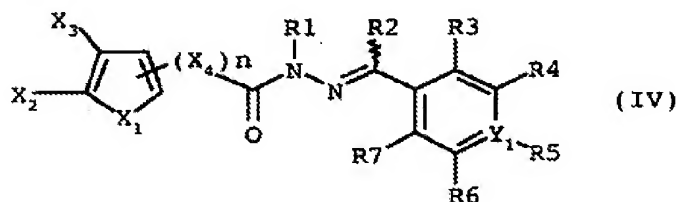
Disease of pending claim 18	Figures of the patent application
Atherosclerosis	FIG.1/FIG.3/FIG.4/FIG.5/FIG.6/FIG.9/FIG.10 FIG.14/FIG.16
Obesity	FIG.2/FIG.3/FIG.4/FIG.5/FIG.9/FIG.10/FIG.13
Arterial Restenosis	FIG.1/FIG.4/FIG.5/FIG.6/FIG.9/FIG.16
Hyperglycemia	FIG.11/FIG.12/FIG.17/FIG.18
Type IIb Diabetes	FIG.11/FIG.12/FIG.17/FIG.18
Cerebral ischemia	FIG.1/FIG.3/FIG.5/FIG.6/FIG.8
Hepatic steatosis	FIG.1/FIG.9/FIG.10
Hypercholesterolemia	FIG.1/FIG.3/FIG.4/FIG.8
Hyper triglyceridemia	FIG.1//FIG.5/FIG.9/FIG.10/FIG.14
Chylomicronaemia	FIG.1

Therefore, in view of the above, withdrawal of the rejection is respectfully requested.

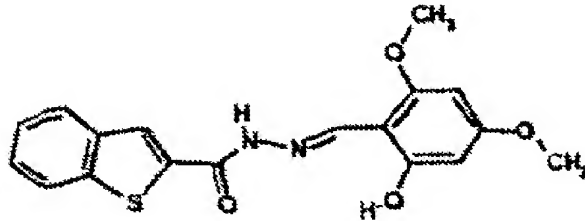
### Claim Rejections-35 USC §103

Claims 1, 3, 4, 6, 7 and 13-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over CAI et al. U.S. 2003/0105140 A1 ("CAI"). This rejection is respectfully traversed for the reasons below.

Claim 1 is directed to compounds of general formula (IV):

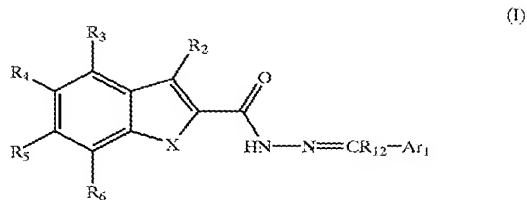


Such compounds include the elected species CGP02-01, or N'-  
[(1E)-(2-hydroxy-4,6-dimethoxyphenyl)methylene]-1-  
benzothiophene-2-carbohydrazide, as recited in claim 6:



The compounds according to the claimed invention are  
useful for treating diseases associated with lipid metabolism  
disorders, e.g., as described in claims 16-18.

The Official Action has maintained that the above  
elected compound falls within the scope of formula (I) of CAI:



In support of this position, *In re Spada*, 911 F.2d 705, 709 15  
USPQ2d 1655, 1658 (Fed. Cir. 1990), was cited. However, *In re  
Spada* concerns the citation where the composition is  
explicitly taught.

However, in the instant case, CAI does not  
explicitly direct one of skill in the art to the claimed  
compound according to formula (I). Instead, CAI describes a  
very broad range of compounds covered by a generic formula.

This broad range of compounds overlaps the compounds described by the instant claim 1.

Moreover, CAI discloses that the compounds are used for treating cancer diseases, and there is no suggestion for treating diseases associated with lipid metabolism disorders.

Thus, the claimed group of compounds, which overlap a relatively small subset of the compounds described by CAI, have an unexpected effect in view of CAI.

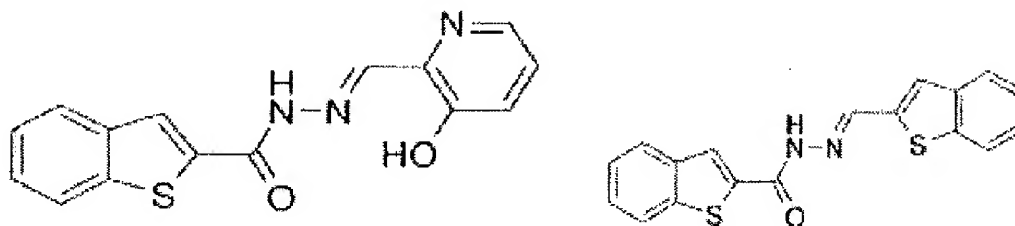
In support of this position, the previously filed reply, Applicant submitted a Declaration under 37 CFR 1.132 by Gerard Marguerie, one of the named co-inventors, to demonstrate that compounds that fall within the scope of CAI, but outside the scope of the claimed compounds do not have the same effect as the claimed invention.

Specifically, the Declaration compared compounds according to CAI with a sulfur atom for the substituent X to correspond to claimed and elected compounds, i.e. which has a sulfur atom a  $X_1$ . That is, compounds of CAI in which X is a sulfur atom are closer to claimed invention (in terms of structure) than compounds, for example, in which X is nitrogen or oxygen.

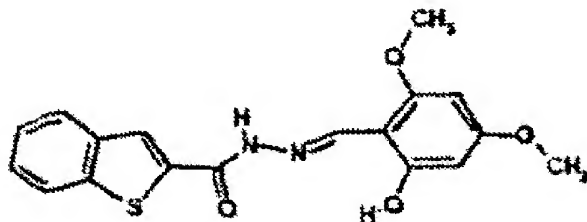
Indeed, according to CAI, the particular aryl group (Ar1) does not affect activity when X is a sulfur atom. That is, in claim 32 of CAI, X is S and Ar1 is "optionally substituted aryl or heteroaryl", and Ar1 may further be

selected from the group in claim 33. Thus, one of ordinary skill in the art would have concluded that the following aryl groups would have be equivalent for the activity desired CAI: (1) substituted aryl group, such as 2-hydroxy-4,6-dimethoxyphenyl, (2) a substituted aryl group such a hydroxyl pyridyl, and (3) a heteroaryl group, such as benzothiophene.

Consequently, in view of claims 32 (and 33) of CAI, the compounds:



should have the same activity as the elected compound:



However, as explained in the Declaration, the elected compound has the claimed therapeutic activity, whereas the other two compounds above do not.

Thus, as the Declaration established that the hydroxyl pyridyl group and benzothiophene group yield a different activity than 2-hydroxy-4,6-dimethoxyphenyl and this

activity was not known to CAI, the specific selection of the claimed compounds that fall within the scope of CAI provide an unexpected therapeutic activity.

Therefore, the claims are not rendered obvious, and withdrawal of the rejection is respectfully requested.

### **Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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